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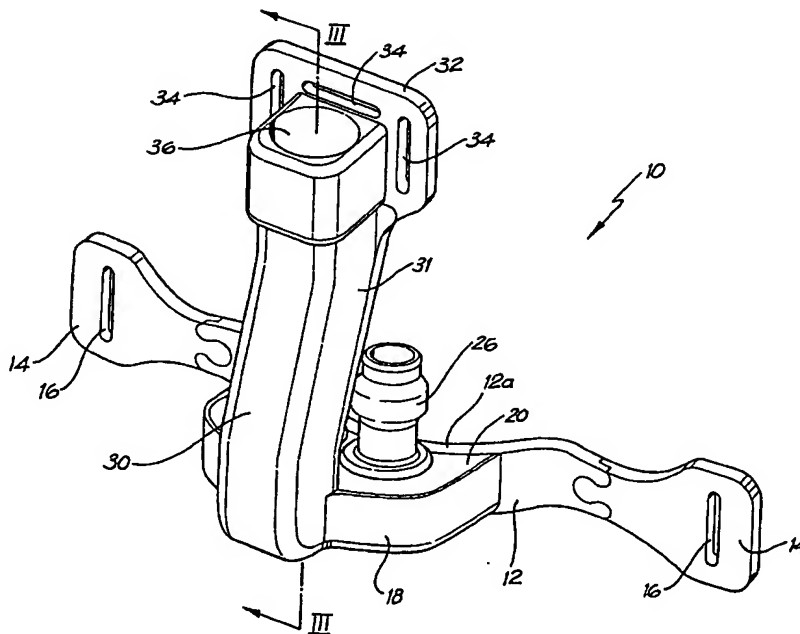
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(54) Title: MASK



(57) Abstract: A mask (10) for supplying gas under pressure to the nasal airway of a human includes a manifold (30) including means (36) for connection to a gas supply means, a gas supply element or elements (26) for providing said gas to the nasal airway without pressurising the exterior of the nose and a flexible strap (12) formed from an elastomeric material for securing the manifold (30) in position. The strap (12) extends either side of the manifold (30) and is shaped to generally conform with the shape of the upper lip and adjacent cheek area to act as a distributed anchor means for the mask (10).

MASK

Field of the Invention

This invention relates to a mask for supplying gases, typically fresh air or oxygen to the airways of humans.

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Background of the Invention

Various different types of masks are used to provide fresh air or oxygen to the airways of humans. A specialised category of masks is used to provide positive pressure to the human airway. Positive pressure applied in this manner has two different goals.

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In a first category, positive pressure is applied to the lungs for the purpose of stabilising the lungs, and in particular for maintaining a minimum inflation level of the small air spaces in which gas transfer occurs (the alveoli). This therapy is very useful in patients with a variety of lung diseases, where the disease process tends to lead to collapse (closure of the airway containing regions of the lung).

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In a second category, the positive pressure is applied to the nasal airway with the intention of maintaining the pressure in, and the patency of, the upper airway. This form of positive airway pressure is known as nasal continuous positive airway pressure (nasal CPAP). This is now the "gold standard" treatment for the condition known as obstructive sleep apnea (OSA), and also for snoring. Obstructive sleep apnea is a condition in which the upper airway closes in sleep, and does so repeatedly. Nasal CPAP, when applied for the duration of sleep, stabilises the upper airway and allows for normal sleep and normal breathing.

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Masks for applying nasal CPAP, or nasal pressure support ventilation have a requirement to be able to deliver pressure and flow and maintain pressures within the mask without permitting leaks. Leaks are undesirable as they can allow the pressure in the mask to drop below a therapeutic level. Leaks may also be an irritation particularly, if the leak causes jets of air/oxygen to be directed into the patient's eye. Leaks interrupt a patient's sleep which is undesirable as interrupted sleep is known to be of much less value than uninterrupted sleep. Leaks may also be noisy. Further, as the masks are for use during natural sleep, a high level of comfort in the fit of the mask is necessary.

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patent No 634994, addresses this problem by making a portion of the wall containing the gas supply port exhibit a degree of flexibility that is greater than that of adjacent regions of the mask so that movement by the connecting gas supply line will be accommodated at least in part by flexing of the wall portion. Whilst both masks produce relatively satisfactory seals they are quite bulky, relatively heavy and ungainly. They have a substantial impact or "footprint" on the patient's face. Neither fully solves the problems of forces acting on the manifold causing leaks.

In existing facial masks, because the straps must anchor onto a rigid point, they are attached to the rigid manifold; the result is that typically the strap leaves the side of the face near the cheeks, and passes through air until it reaches the lug on the manifold. This "floating" part of the strap, provides a significant weakness and adversely affects the integrity of the seal when the patient's head moves. When the subject rolls onto their side, this floating part of the strap is easily distorted, and pulls on the mask and leads to a leak.

All masks have to take account of the geometry of the patient's face, in particular the geometry of the patient's nose. Most existing masks are quite bulky and can be quite obtrusive, particularly for patients who either wear glasses or wish to read while falling asleep or who have facial hair.

Beards also adversely affect the sealing of conventional masks. Often patients who suffer from sleep apnea are obliged to shave their beards if they wish to receive treatment via a nasal mask.

One mask which does not require a patient to shave, and allows the wearing of glasses is the Respironics® SimplicityTM nasal mask, manufactured by Respironics Inc., of 1501 Ardmore Boulevard, Pittsburgh, Pennsylvania. That mask provides a bubble type seal which fits over a patient's nose only extending up to the bridge of the nose and around the sides. While this reduces the "footprint" of the mask on the patient's face, the reduction in the size of the sealing bubble compared with the traditional bubble masks described above reduces the area of sealing and makes the mask much more susceptible to torsional effects caused by movement of the patient's head, pulling on the gas supply pipe etc. The seal is much less "stable" than traditional bubble masks.

US Patent No 4,782,832 adopts a different approach to the above described masks in providing what it terms a "nasal puff". The gas delivery mask/nasal puff of US 4,782,832 fits only in the nose of the patient and is

a manifold including means for connection to a gas supply means, and a pair of spaced apart gas outlets;

a pair of gas delivery elements insertable into a patient's naris defining a gas flow passageway therethrough coupled with a corresponding gas outlet
5 for conveying gas from the manifold through and out the passageway, the elements being configured to present a distal end portion for insertion into a nares of a human;

a flexible strap formed from an elastomeric material for securing the manifold in position on the face of the human, the strap extending either side
10 of the manifold and being shaped and configured to generally conform to the shape of the upper lip and adjacent cheek area of the human to act as a distributed anchor means for anchoring the nasal mask to a human's face.

The advantage of the present invention, in contrast with the prior art US 4,782,832, is that the gas delivery elements do not function as the primary
15 anchor means but merely act as a delivery/sealing means for the air pressure. Instead, anchoring is provided by the strap which provides an elongate anchor means with a large contact area to the face which is therefore very secure, movement being prevented by a high degree of contact by the strap and the skin with consequently high frictional force. The separation of the
20 sealing functions and the anchoring functions is also a major step forward over the bubble type masks of AU 643994 et al where the bubble membrane acts not only as the seal around a patient's nose but also has to anchor the mask to the patient's face. By separating the sealing and anchoring functions the seal is less likely to be broken or adversely affected by movement of the
25 patient's head. The strap is made from a flexible elastomeric material such as silastic and typically the manifold will be formed from the same flexible material so that the manifold itself, is also deformable. The gas delivery elements may also be formed from silastic.

The strap may form one side of the manifold.

30 Although the nasal mask could theoretically function with two anchor points, a third anchor point is preferable. In one preferred embodiment, this is provided by a nose bridging portion which extends from the manifold and is shaped to span the patient's nose in use. A distal end of the bridging portion defines a pad which may include a slot for attachment to a harness
35 and an inlet adapted for coupling the nasal mask with a source of gas. The extension of the manifold is preferably configured, so that in use, when the

one of the patient's eyes and the contiguous side of the patient's nose. In this way the pipes function as a barrier between the seal around the patient's nose and the patient's eyes and deflect any gas or air leaks escaping from the seal away from the patient's eyes which are sensitive to air leaks. This mask also
5 has the advantage of having a very low profile compared to existing masks

In a yet further embodiment a further pipe may extend along one side of the strap typically with one wall of the pipe being defined by the strap. One pipe could be used to supply air to the mask and the other for airflow out of the mask. the out flow pipe at least would typically include a one way
10 valve. Meters could be placed in the two pipes to measure in and out gas flow, or gas concentrations or the like. Such a mask could be useful for treating and/or monitoring stroke victims and the like who may require a supply of pressurised air or oxygen, the low profile of the mask being a particular advantage.

15 The type of bubble described above in which the interior, but not the exterior of the nose/nostrils is subject to raised pressure may also be used in masks where the strap does not define a distributed anchor means.

Thus in a yet further aspect of the present invention there is provided a mask for supplying a gas under pressure to the nasal airway of a human's
20 nose, the nose having a side, and a base defining nares comprising:

a manifold including means for connection to a gas supply means;

a flexible shaped bubble membrane made from a elastomeric material, the bubble membrane defining an aperture of about the size of the base of a human nose;

25 means for locating and securing the aperture of the bubble membrane at the base of the human's nose;

means for supplying air under pressure from the manifold to the bubble membrane wherein in use, when gas is supplied under pressure to the bubble membrane with the aperture located at the base of the nose, gas under
30 pressure flows into the nares expanding the anterior nasal cavities thereby reducing the resistance to air flow, and simultaneously causing a skin contact region of the base of the nose to mould and conform to the expanding bubble membrane, thus providing an effective seal.

35 Brief Description of the Drawings

Figure 20 is a schematic drawing illustrating the use of the mask and harness of Figure 16.

Figure 21 is a front view of a variant of the mask of Figure 15: and

Figure 22 is a section through the mask of Figure 21.

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Detailed Description of Preferred Embodiments

Referring to the drawings, Figures 1 to 3 show a first nasal mask 10. The mask includes a lower strap 12 at each end of which are disposed pads 14, which are enlarged relative to the width of the strap. Each pad 14 defines
10 a slot 16 for the attachment of a harness, not shown in Figures 1 to 3, to the mask. The strap is made from a flexible elastomeric material such as silastic and is shaped so that the central area 12a of the strap is curved to generally conform to the shape of the area of a human face between a human's mouth and the base of their nose (see Figure 2). Note that hereinafter the human is
15 referred to as a patient. On the opposite side of the central area of the strap 12a which contacts a patient's face, there is a manifold or chamber 18. The manifold is also made from the same flexible elastomeric material as the strap. The manifold has a generally planar upper surface 20 and a generally planar lower surface 22. Two circular outlets 24 are provided in the
20 generally planar upper surface to which are attached two gas delivery elements or nasal prongs 26 which, in use, when the mask is correctly positioned on a patient's face, locate and seal inside each naris of the patient's nose. The design of the nasal prongs 26 is shown in more detail in Figure 4 and discussed in detail below.

25 An inlet pipe 30 extends into the front of the manifold. The inlet pipe defines a bridge portion 31 which extends from the manifold to an anchor pad 32 at the distal end of the pipe remote from the manifold. The bridge portion 31 is aligned generally with a patient's nose. In use, when the mask is fitted to a patient (see Figure 6), the bridge portion 31 extends above and
30 generally parallel to the upper surface of a typical patient's nose to a point on the patient's forehead just above their nose. The pad 32 includes three slots 34 for receiving a harness 110 in use such as that shown in Figure 16 which harness is shown in use with a different mask embodiment. The distal end of the pipe 30 also defines a port 36 for receiving an air delivery pipe.

35 Figure 4 shows the nasal prong 26 in more detail. The prong is generally rotationally symmetrical about its central axis. The base 50 of the

expands outside the nose and partly in the opening of the nostril, thus providing a double seal.

The anchoring of the mask and manifold by the strap portion 12a means that the nasal prongs only have to seal and deliver air to the patient's nose and do not have to anchor the mask in position. This contrasts with existing masks where sealing and anchoring are performed by the same elements. One advantage of this is that the nasal prongs do not cause any substantial irritation to the patient's nasal epithelium.

The structure of the bridge portion and in particular, the way it passes over the top of a patient's nose, means the mask is less obtrusive than existing masks and is consequently relatively comfortable.

In a preferred embodiment, a flow meter 106 may be provided in the manifold.

Figures 7 to 11 illustrate a second embodiment of the present invention which has the advantage of providing reduced resistance to air flow, in use. The maximum resistance to air flow through a nose occurs at the start of the nasal passage adjacent the nostril or naris. The use of nasal prongs of the type shown in US 4,782,832 reduces the dimensions of the passage and thus can increase resistance further. The embodiment of Figures 7 to 11 addresses this problem by providing a flexible bubble membrane which expands and seals around the base of a patient's nose but which does not penetrate the naris. This second embodiment retains the advantage of the separation of the sealing and anchoring functions.

The second embodiment 60 shares a large number of components with the first embodiment which share the same reference numerals in the drawings and the detailed description of those common components is not repeated in detail here.

In the second embodiment, the prongs and upper surface of the manifold are replaced with a flexible shaped "bubble" 62, also shown in Figure 8. The bubble may be made from a flexible elastomeric material (such as silastic). A generally kidney bean shaped opening 64 is provided in the centre of the bubble (see Figure 9). The bubble ranges in thickness from t_1 , about 0.2 - 0.4mm at the edge around the opening 64 to t_2 about 1.5mm at its base where it joins the manifold (see Figure 9).

With reference to Figures 11a and 11b, in use, when the mask is correctly positioned on a patient's face with the manifold disposed between

Figure 15 shows a yet further embodiment of the invention in which instead of the bridging portion 31 extending over a patient's nose, in the mask 80 of Figure 15 two pipes or ducts 82 extend from the manifold 18 to the port 36 around the sides of a patient's nose. In use (see Figure 20) the pipes extend either side of the patient's nose, so that they do not pressurise the patient's nose. This design minimises the foot print of the mask on the patient's face and increases patient comfort. The pipes are curved outwardly to avoid a patient's nose so that the pipes do not prevent the patient's nose from expanding under pressure and do not compromise the seal at the bubble membrane 62 to the base of the patient's nose. The pipes are also angled away from the patient's eye, to allow the patient to see clearly while the mask is on and to allow the patient to read to sleep. As is best seen in Figure 19 the two pipes are shaped to closely fit to the contours of the patient's face and may also be made relatively flexible to enable this. In this way the pipes function as a barrier between the seal around the patient's nose and the patient's eyes and block/deflect any gas or air leaks escaping from the seal away from the patient's eyes which are sensitive to air leaks.

Figure 16 shows the mask fixed to a harness 110 for use by a patient.

A further feature of the invention which is illustrated in Figure 17 in particular shows that the pipes 82 extend away from the manifold either side of, and spaced apart from the bubble membrane 62. This feature assists in separating the anchoring function (to which the pipes 82 may contribute from the sealing function provided by the bubble 62.

Figure 18 illustrates that the rear wall 126 of the manifold is considerably thinner than the strap 12, typically of the order of 0.2 to 0.4mm. This improves the sealing of the bubble 64 to the patient's face.

Figure 20 also illustrates a further modification of the invention in which air inflow and air outflow is monitored. One of the straps 12 defines a pipe which may be attached to the strap or may have one side wall defined by the strap. Air may flow in through port 36 and flow out via a port 120 at the end of strap/pipe 12a. One or more one way valves, not illustrated, would be provided to control the air flow. A meter 122 could be used to measure either the rate of airflow or concentrations of gases such as oxygen or carbon dioxide in the outflow. A similar metering means 124 could be provided in the gas inflow, if desired. Such a mask could be useful in treating stroke victims and the like where a controlled supply of pressurised

Claims

1. A mask means for supplying gas under pressure to the nasal airway of a human comprising:
 - a manifold including means for connection to a gas supply means;
 - 5 a gas delivery element or elements for providing gas under pressure to the nasal air way of a human without pressurising the sides of the nose;
 - a flexible strap formed from an elastomeric material for securing the manifold in position on the face of a human, the strap extending either side of the manifold and being shaped and configured to generally conform with
 - 10 the shape of the upper lip and adjacent cheek area of a human to act as a distributed anchor means for anchoring the nasal mask.
2. A mask as claimed in claim 1 wherein the gas delivery elements comprise nasal prongs which locate inside a human's nostrils.
3. A mask means for supplying gas under pressure to the nasal airway of
- 15 a human, comprising:
 - a manifold including means for connection to a gas supply means, and a pair of spaced apart gas outlets;
 - a pair of gas delivery elements insertable into a patient's naris defining a gas flow passageway therethrough coupled with a corresponding gas outlet
 - 20 for conveying gas from the manifold through and out the passageway, the elements being configured to present a distal end portion for insertion into a naris of a human;
 - a flexible strap formed from an elastomeric material for securing the manifold in position on the face of the human, the strap extending either side
 - 25 of the manifold and being shaped and configured to generally conform to the shape of the upper lip and adjacent cheek area of the human to act as a distributed anchor means for anchoring the nasal mask to a human's face.
4. A mask as claimed in any preceding claim wherein the strap defines one side of the manifold.
- 30 5. A mask as claimed in any preceding claim wherein the strap and manifold are made from a flexible elastomeric material.
6. A mask as claimed in any preceding claim wherein a nose bridging portion extends from the manifold and is configured to pass around or over a patient's nose in use to define the further anchoring point distal from the
- 35 manifold.

14. A mask as claimed in any preceding claim wherein a pipe extends along at least one side of the strap.

15. A mask for supplying a gas under pressure to the nasal airway of a human's nose, the nose having a side, and a base defining nares comprising:

5 a manifold including means for connection to a gas supply means;

a flexible shaped bubble membrane made from an elastomeric material, the bubble membrane defining an aperture of about the size of the base of a human nose;

10 means for locating and securing the aperture of the bubble membrane at the base of the human's nose;

means for supplying air under pressure from the manifold to the bubble membrane wherein in use, when gas is supplied under pressure to the bubble membrane with the aperture located at the base of the nose gas under pressure flows into the nares expanding the nares thereby reducing the resistance to air flow through said nares.

16. A mask as claimed in claim 15 wherein the means for locating and securing the aperture of the bubble membrane at the base of the human's nose include a flexible strap formed from an elastomeric material, the strap extending either side of the manifold and being shaped and configured to generally conform with the shape of the upper lip and adjacent cheek area of a human to act as a distributed anchor means for anchoring the nasal mask.

17. A mask as claimed in claim 15 or 16 wherein the strap defines one side of the manifold.

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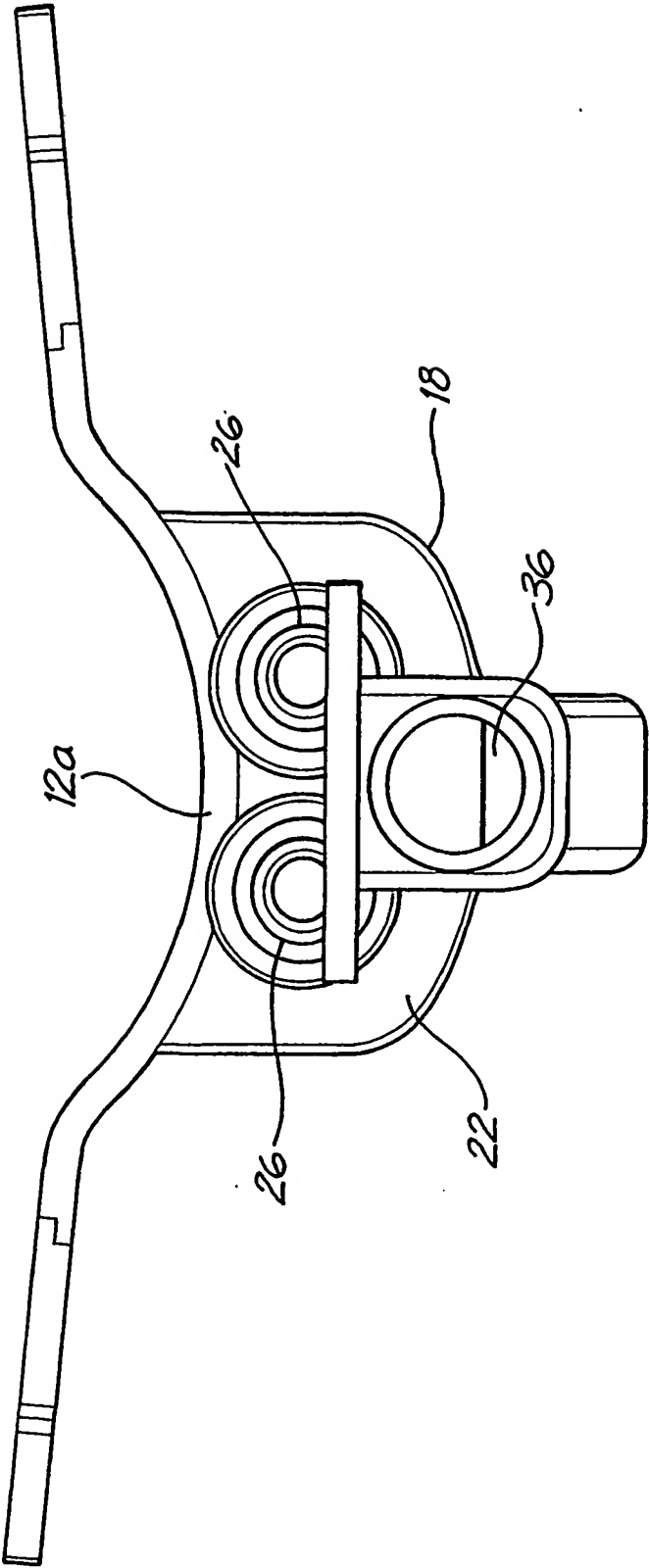


FIG. 2

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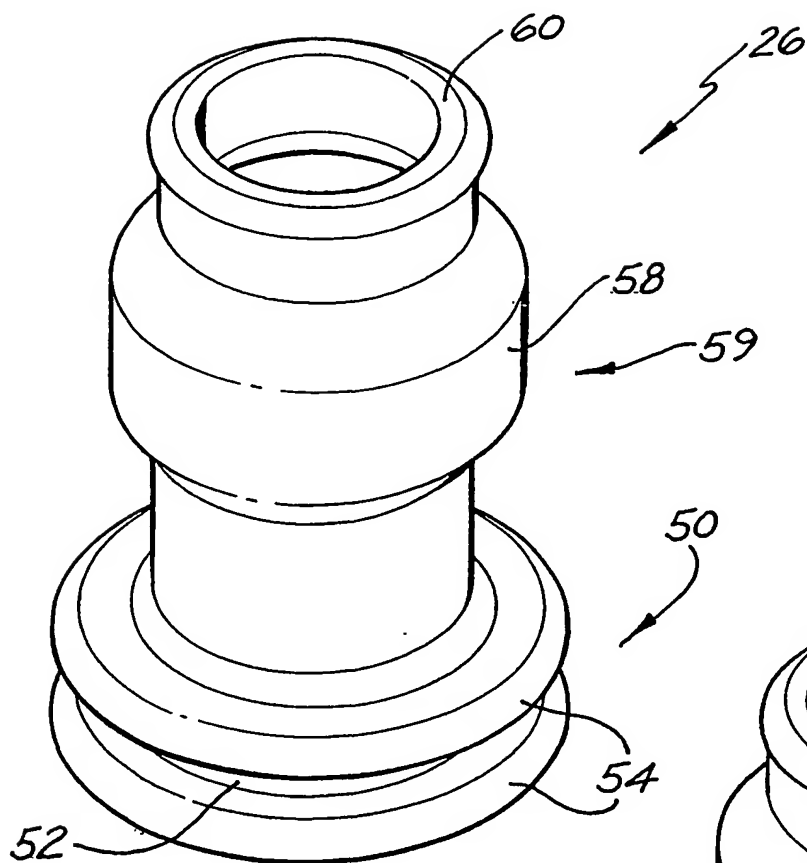


FIG. 4

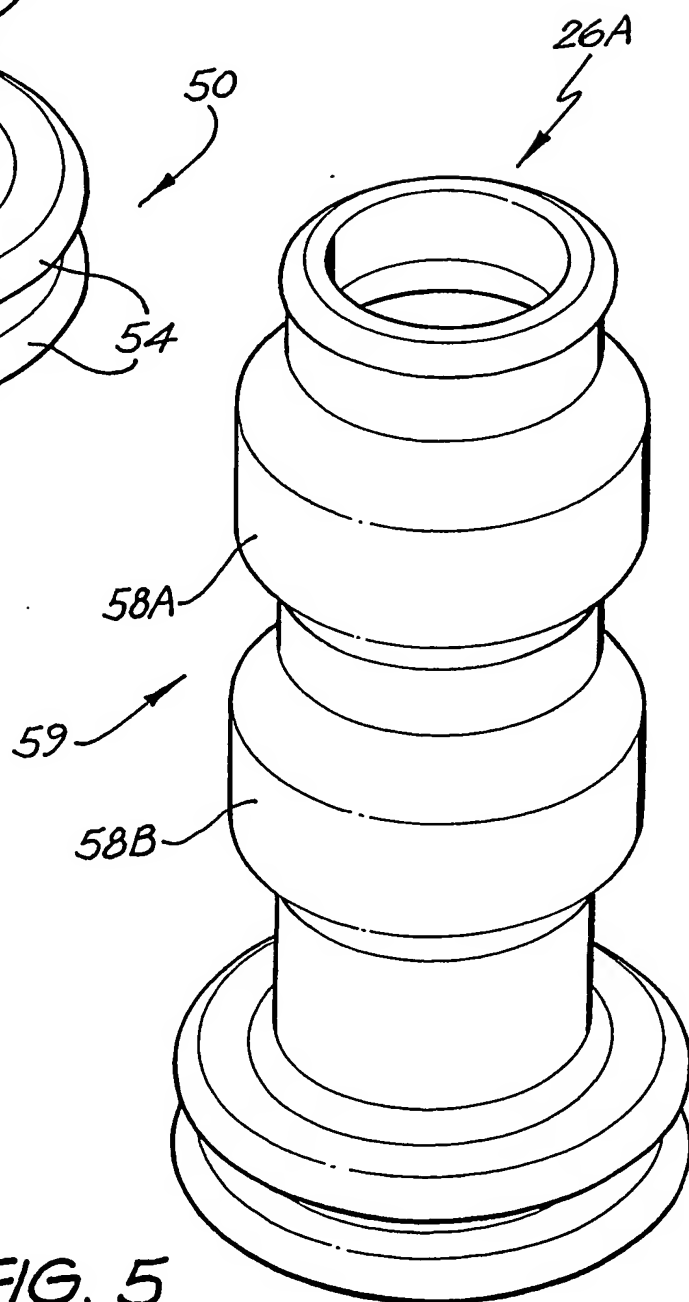


FIG. 5

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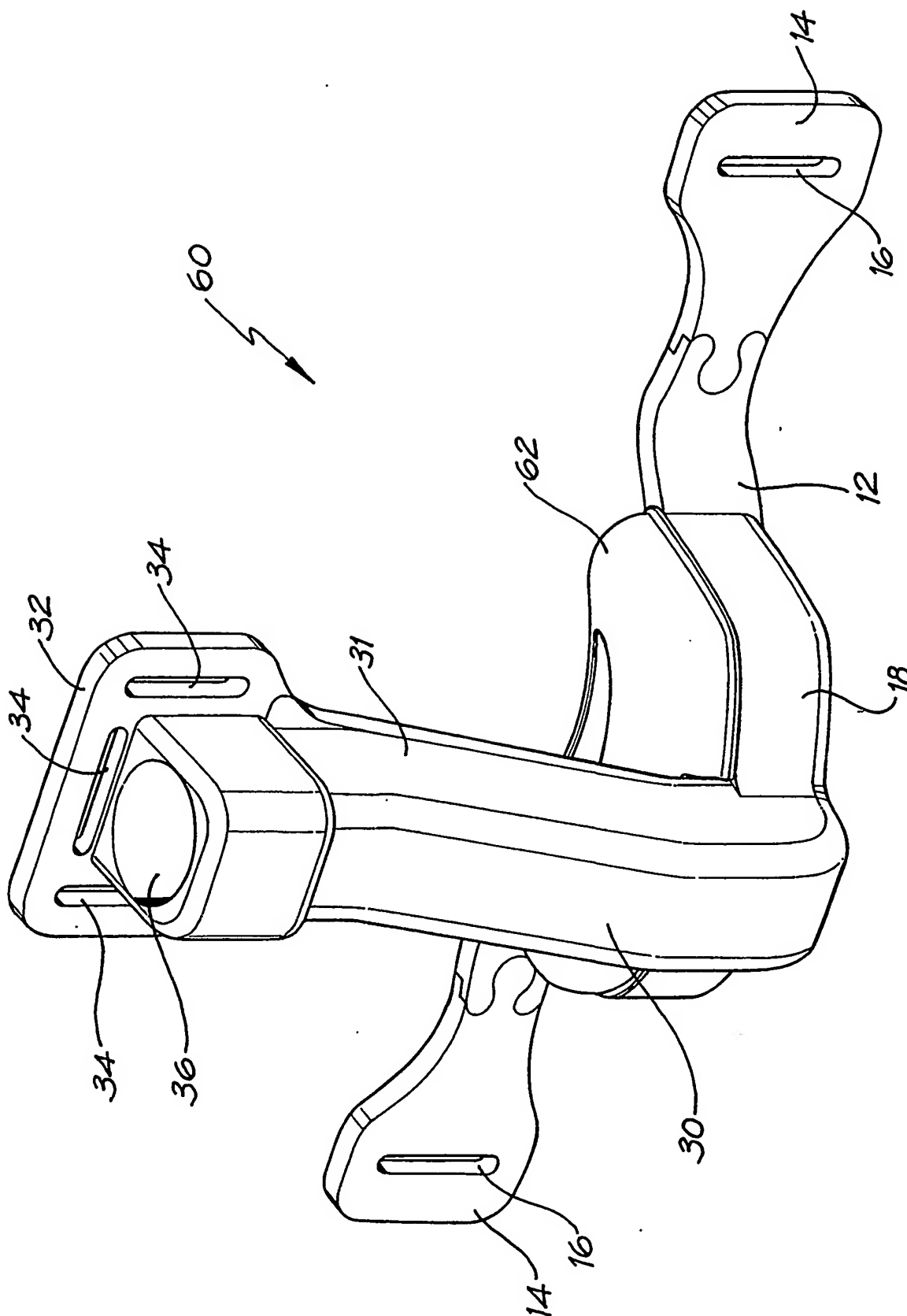


FIG. 7

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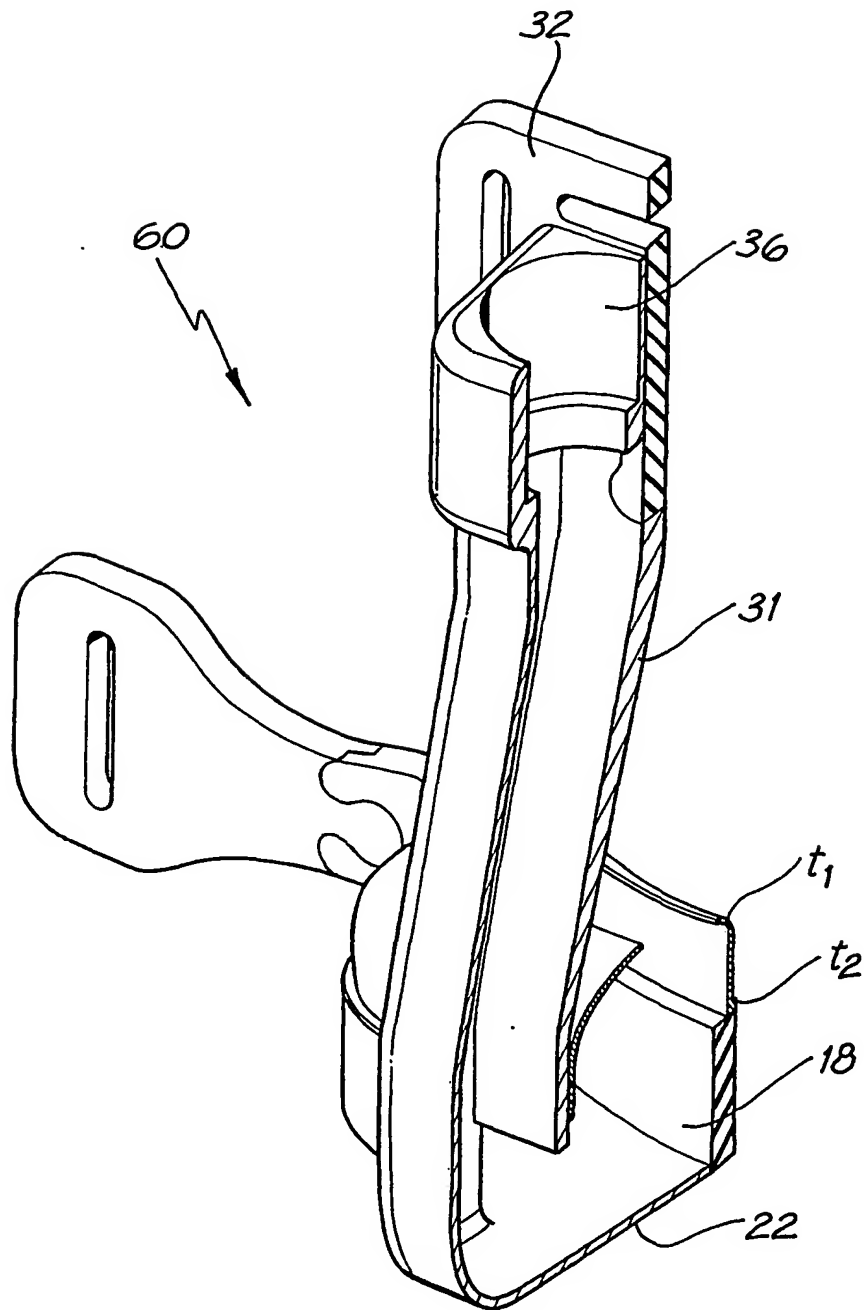


FIG. 9

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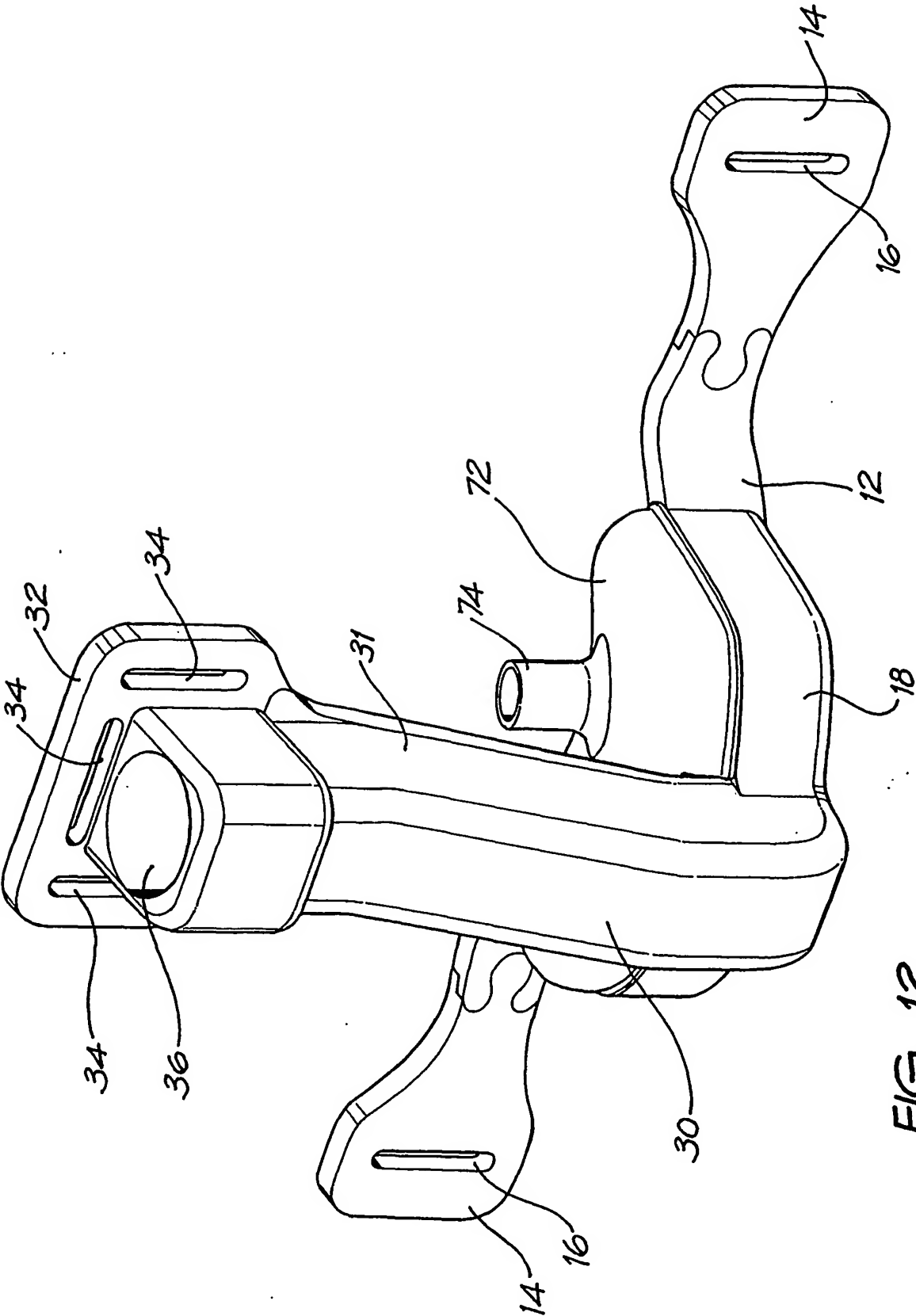


FIG. 12

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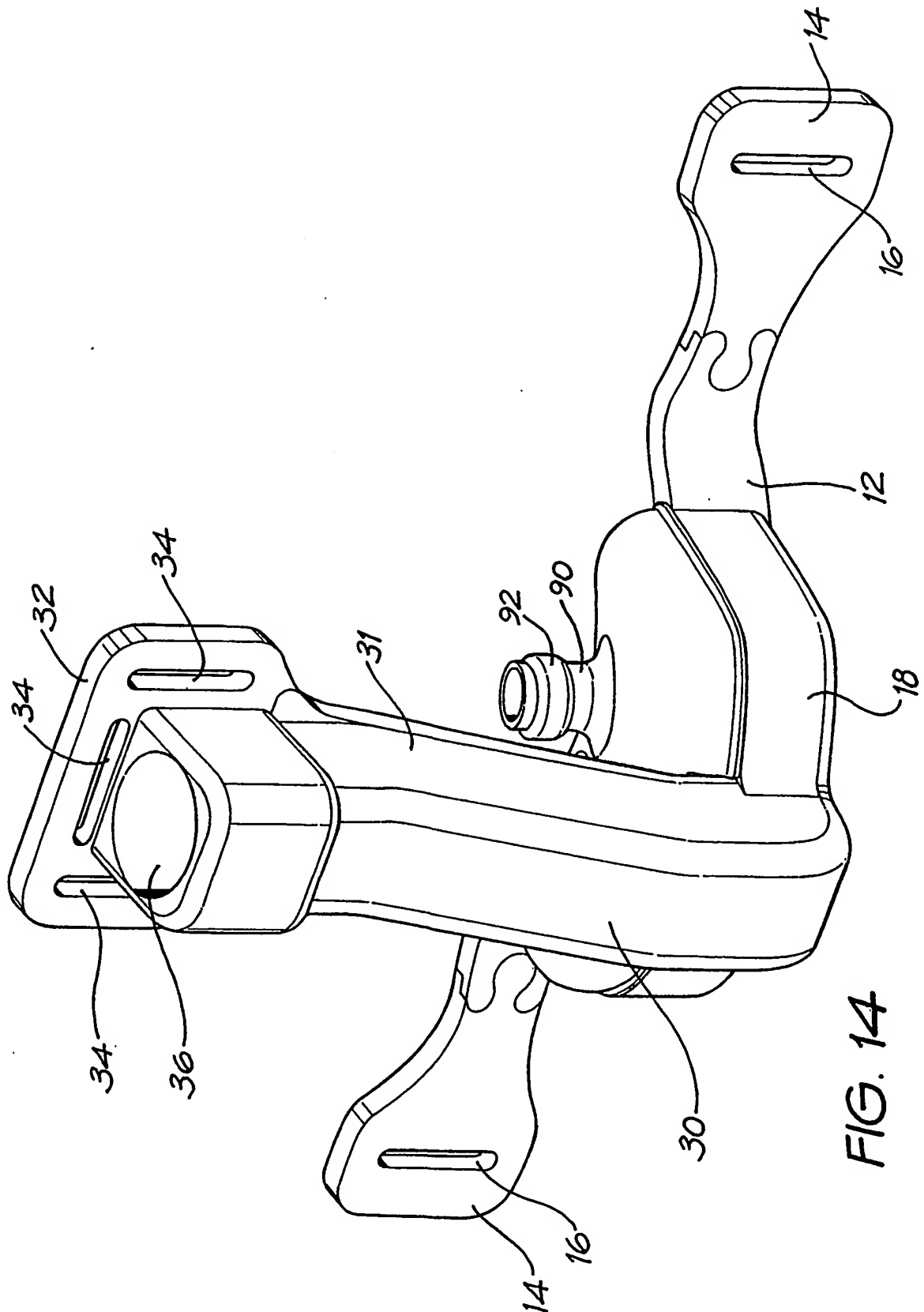


FIG. 14

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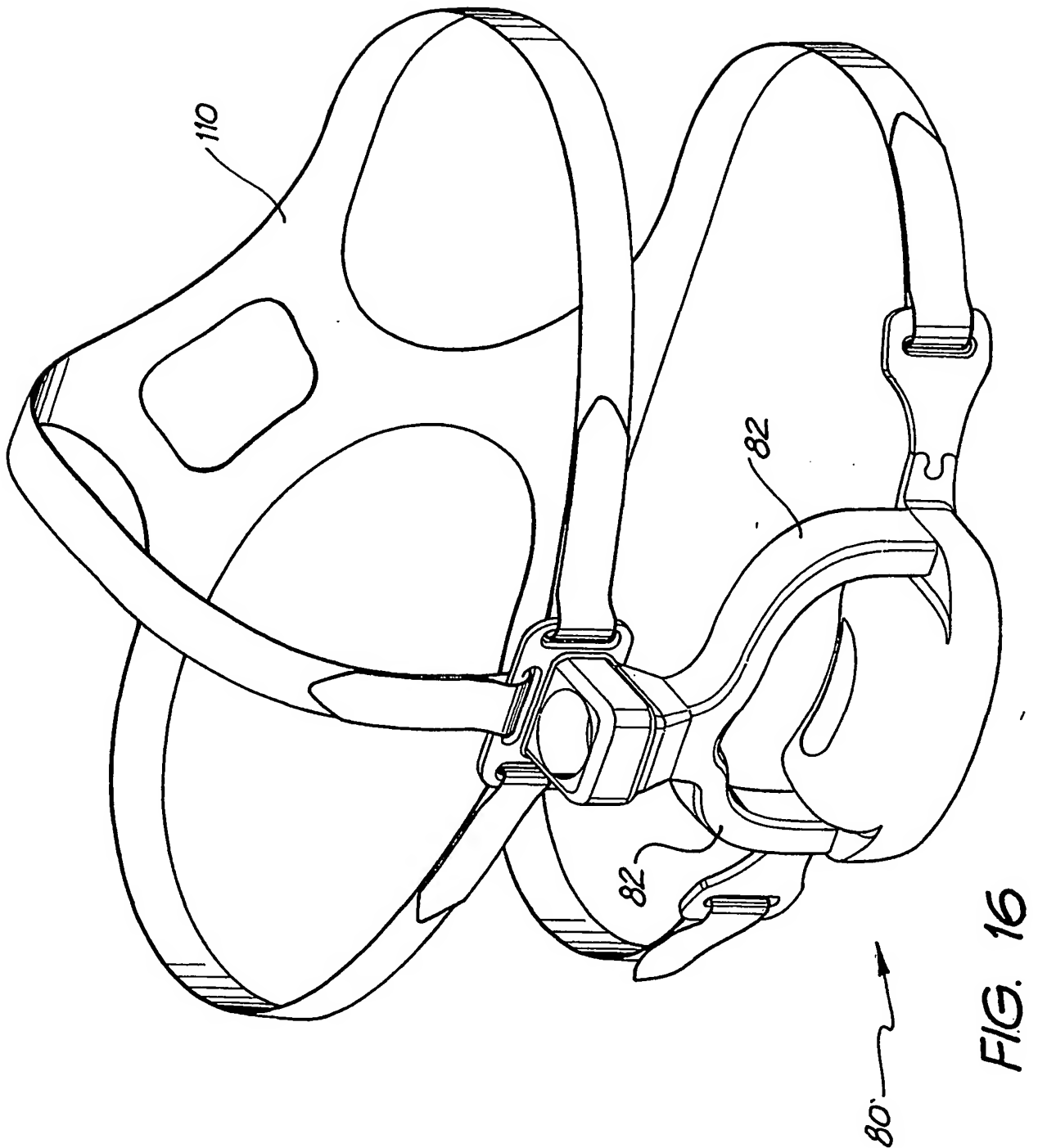


FIG. 16

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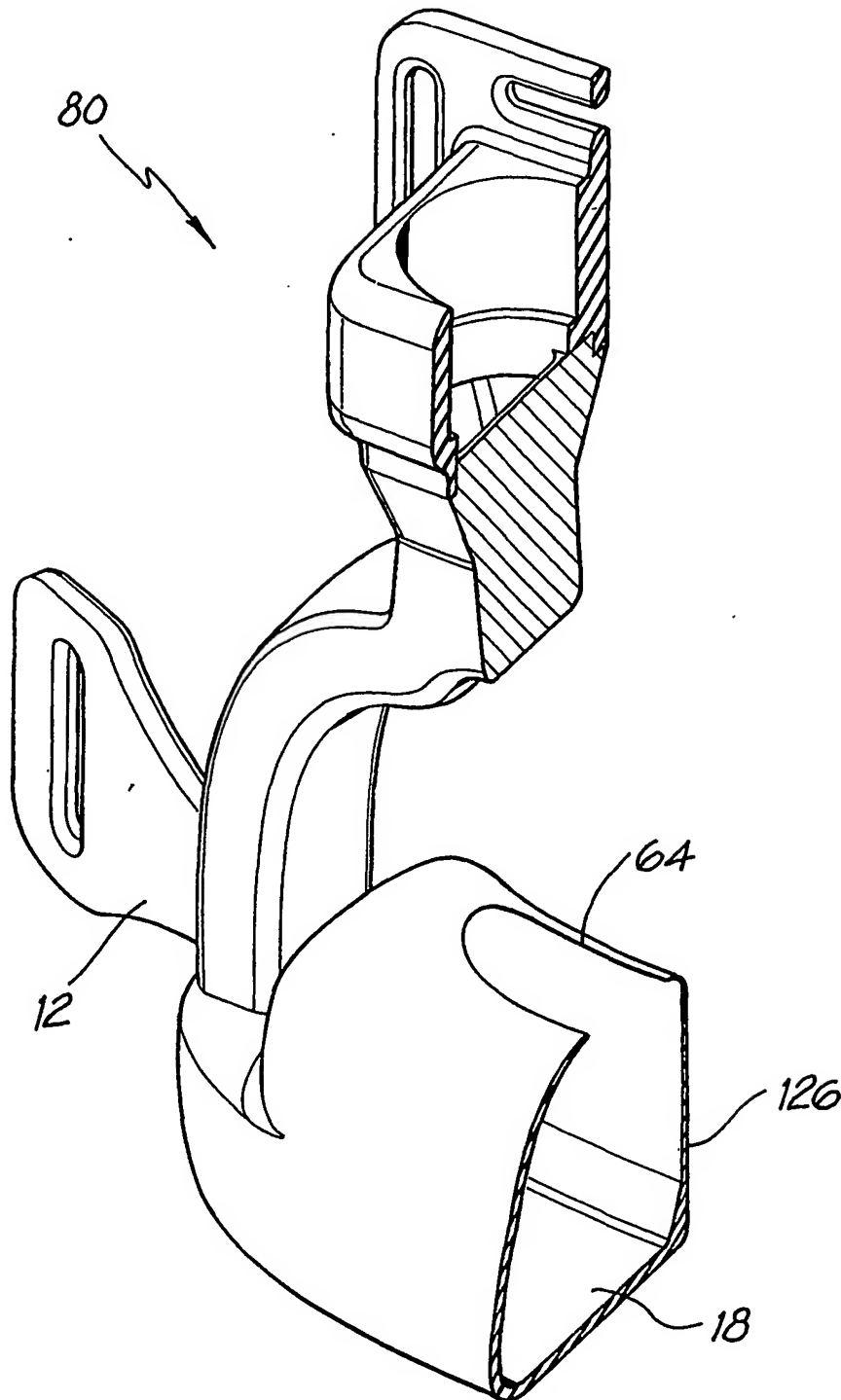


FIG. 18

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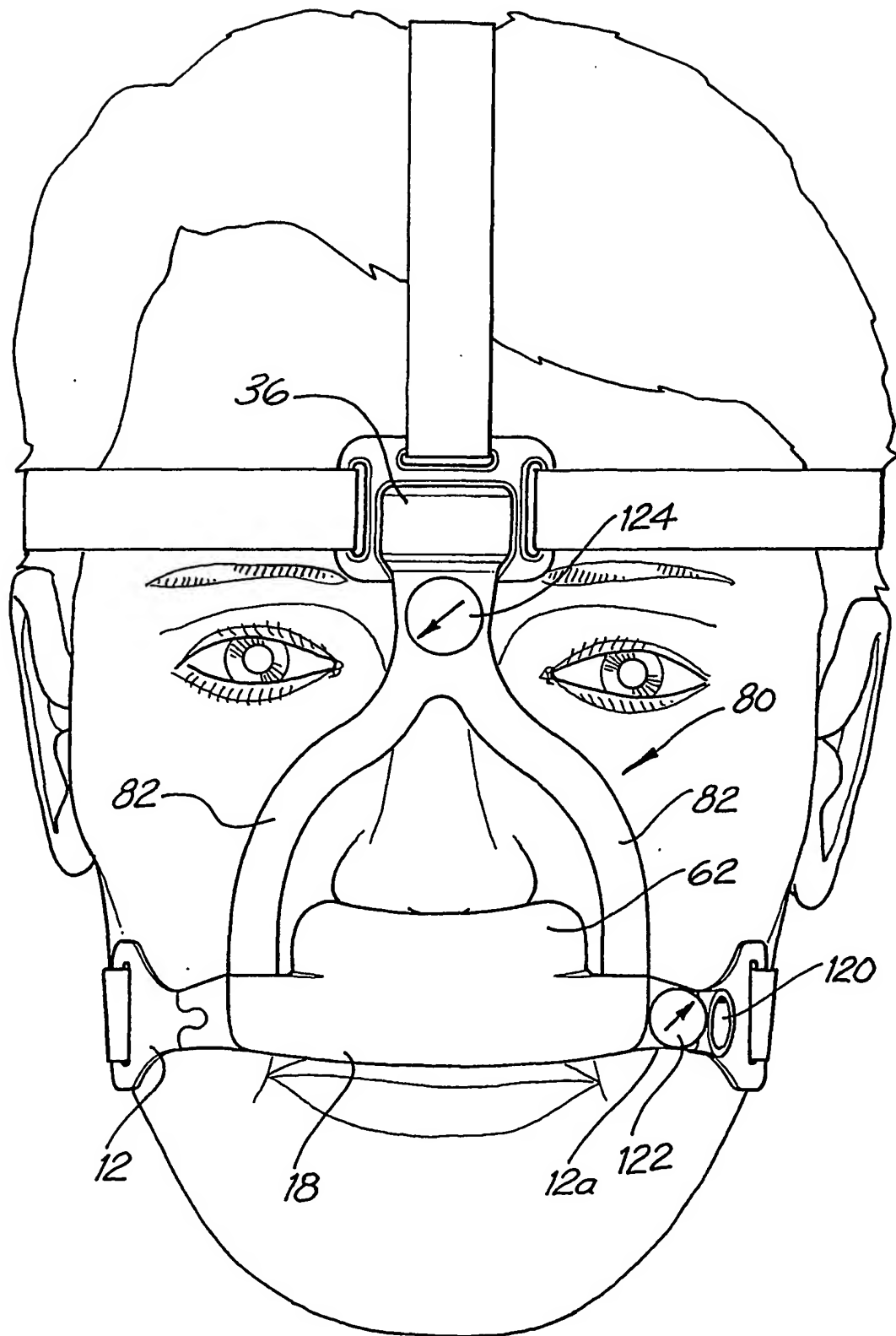
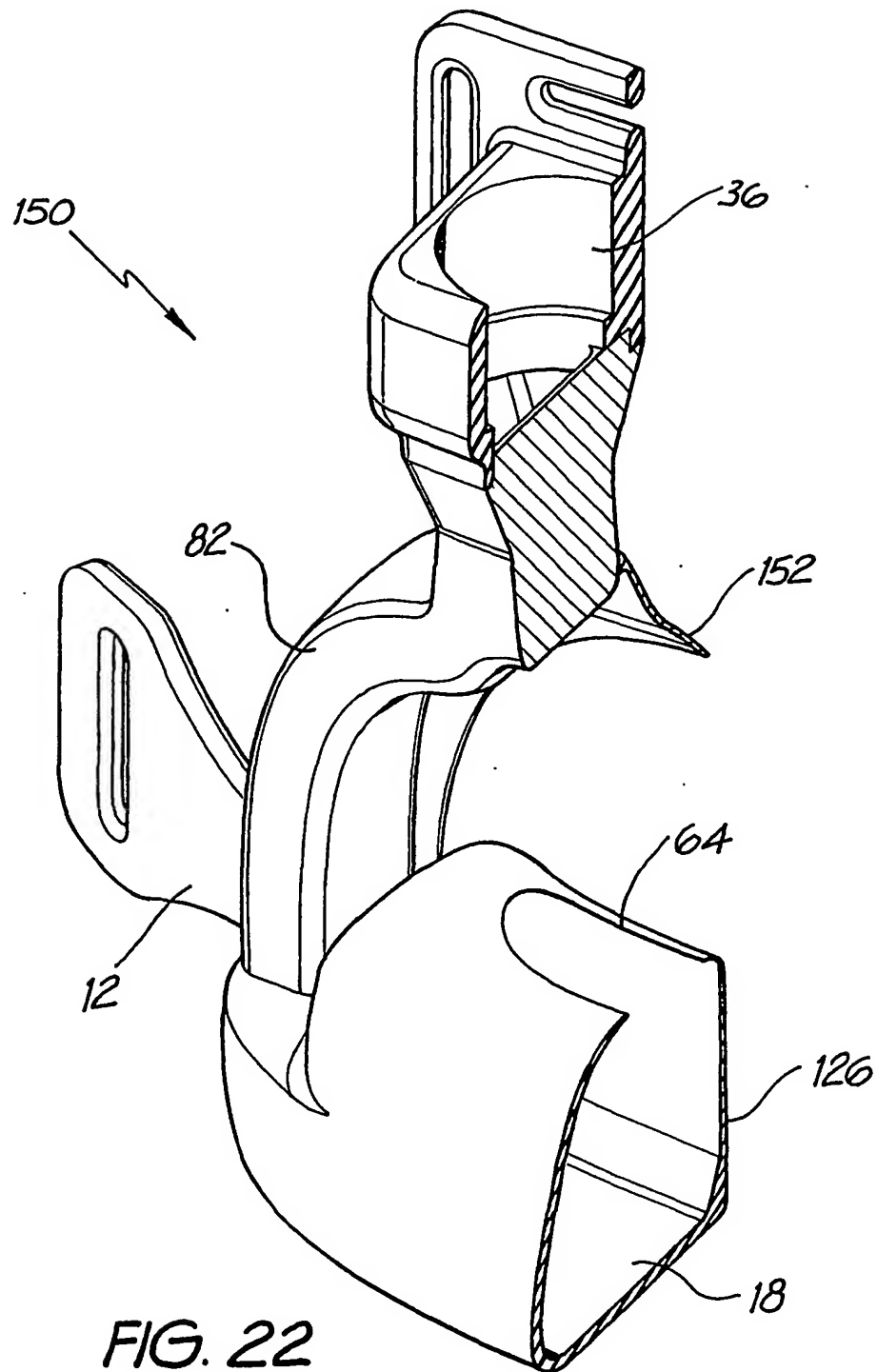


FIG. 20

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INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU01/00721

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	9904842	AU	85962/98	EP	998319	US	6119694
US	5724965	AU	54598/96	AU	89312/98	CA	2177524
		EP	747078	JP	9010311		
WO	74758						
							END OF ANNEX